**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION**
**DECISION SUMMARY**
**DEVICE ONLY TEMPLATE**

## A. 510(k) Number:

K032657

## B. Analyte:

Blood glucose

## C. Type of Test:

Quantitative enzymatic electrochemical sensor

## D. Applicant:

Home Diagnostics, Inc.

## E. Proprietary and Established Names:

TrueTrack Smart System Blood Glucose Meter
TrueTrack Smart System Blood Glucose Test Strips
TrueTrack Smart System Glucose Control Solutions (low and high)

## F. Regulatory Information:

1. Regulation section:
   21 CFR § 862.1345, Glucose test system
   862.1660, Quality control material (assayed and unassayed)
2. Classification:
   Class II
3. Product Code:
   CGA, Glucose Oxidase, Glucose
   NBW, Over the Counter Blood Glucose Test System
   JJX, Single (specified) analyte controls (assayed and unassayed)
4. Panel:
   Clinical Chemistry (75)

## G. Intended Use:

1. Indication(s) for use:

The TrueTrack Smart System Blood Glucose System is intended for the quantitative determination of glucose in human whole blood taken from the finger or forearm. The System is intended to be used to assist the patient and healthcare professional in the management of diabetes.

2. Special condition for use statement(s):

For professional, point of care, and home use.

3. Special instrument Requirements:

Requires the TrueTrack Smart System Blood Glucose Meter

**H. Device Description:**

The TrueTrack Blood Glucose System is comprised of a glucose reagent test strip, a handheld electronic meter, and quality control solutions (low and high glucose levels). A lancing device, sterile lancets, detailed instruction booklet, quick reference guide for operating the system, a logbook for recording test results, and a carrying case are also included with the system.

**I. Substantial Equivalence Information:**

1. Predicate device name(s):
   One Touch Ultra™ Blood Glucose Test System (Selfcare, Inc.)
2. Predicate K number(s):
   K002134
3. Comparison with predicate:

The device and the predicate have the same intended use, recommended sample, reagent form, enzymatic methodology, assay detection method, sample procurement procedure, power source, sample size, relative humidity range, general dimensions and weight, and measurement range. Both also offer test results that are calibrated to be comparable to plasma glucose measurements.

| Differences | | |
|---|---|---|
| **Item** | **Device** | **Predicate** |
| Calibration | Electronic Code Chip | Manual (button) |
| Test Time | 10 seconds | 5 seconds |
| System Operating Temperature Range | 50°F - 104°F | 43°F - 111°F |
| Where Device Used | Home, or by Healthcare Professional | Home |

**J. Standard/Guidance Document Referenced (if applicable):**

NCCLS

- Method Comparison and Bias Estimation Using Patient Samples
- Labeling of Home-Use In Vitro Testing Products

Write It Right

**K. Test Principle:**

The TrueTrack System's operating principle is based on an electrochemical method using meter and reagent sensors designed for capillary blood glucose testing. The user inserts a test strip into the meter, causing the meter to turn on. While the test strip is in the meter the user obtains a blood or glucose control sample, and then applies the sample to the test strip by touching the edge of the test strip to the sample. The meter sounds a tone when an adequate amount of sample has been applied to the test strip and the test begins. The meter's liquid crystal display (LCD) shows a test countdown from 10 seconds. When the test is complete, the meter displays the glucose result.
The TrueTrack Blood Glucose Test Strip is an electrochemical biosensor that fits into the handheld meter. When blood or glucose control solution is applied to a test strip, the sample flows into the sample chamber of the strip. At the distal end of the sample chamber, the force of sample flow is terminated, caused by the gap in the vent area. The glucose measurement sequence is initiated only when the meter detects a full sample chamber. Glucose measurement is based on electrical potential caused by the reaction of glucose with the reagents contained on the strip's electrodes. The glucose in the sample is oxidized by the enzyme glucose oxidase, producing gluconolactone and potassium ferrocyanide. The amount of potassium ferrocyanide produced by the oxidation of glucose is proportional to the amount of glucose in the sample. The potassium ferrocyanide is oxidized at the surface of the measurement electrodes when a specified voltage is applied across the electrodes by the meter. The resulting current is measured and converted to glucose concentration by the meter.

**L. Performance Characteristics (if/when applicable):**

1. Analytical performance:
    *a. Precision/Reproducibility:*

This submission is for the addition of forearm alternate site testing to the claims that were originally cleared for this device. Precision performance was established for this device in K030703.

*b. Linearity/assay reportable range:*

The sponsor reports that the alternate site testing does not change the assay's reportable range (cleared previously K030703). The TrueTrack Smart System will accurately measure glucose levels from 20 – 600 mg/dL (1.1 – 33.3 mmol/L). Linearity performance was established for this device in K030703.

*c. Traceability (controls, calibrators, or method):*

Two levels of control material, the TrueTrack Smart System Glucose Control Solutions, are provided in two levels. Controls are aqueous materials containing known concentrations of dextrose (glucose), stabilizers, buffers preservatives, and dyes. Targeted concentrations of the control(s) are 35 mg/dL dextrose (low) and 110 mg/dL dextrose (high). The controls were cleared with the test system (K030703).

*d. Detection limit:*

Not applicable in this submission. This submission is for the clearance of alternate site testing for a cleared device (see K030703).

*e. Analytical specificity:*

Abnormally high doses of acetaminophen will affect accurate test results. Hyperglycemia with hyperosmolarity, with or without ketosis, and thickened blood caused by dehydration may affect accurate test results (see K030703).

The TrueTrack Smart System will accurately measure glucose from donors exhibiting the following (see K030703):

- 30 – 55 % hematocrit
- elevated total blood cholesterol and triglycerides
- salicylate within expected blood concentrations
- testing at altitudes up to and including 10,150 feet.

*f. Assay cut-off:*
Not applicable.

2. Comparison studies:

*a. Method comparison with predicate device:*

Method comparisons were performed at 4 clinical sites to compare performance of the TrueTrack Glucose system with the predicate device and a gold standard method. Measurements of blood glucose from the forearm were done in duplicate to determine the equivalence of alternate site testing. Forearm samples were taken by the healthcare professional and used to test the comparative devices in duplicate. Two additional capillary samples were taken from each patient for measurement using a gold standard method and for determination of the patient's hematocrit. In these studies, no effort was made to assure that patients had steady state levels of blood glucose. Results are summarized below by site and combined data. (RMSE = Root Mean Square Error)

**Device vs. Predicate (performed by Healthcare Professional)**

| Site | 30 | 31 | 32 | 33 | ALL |
|---|---|---|---|---|---|
| N | 51 | 50 | 45 | 48 | 194 |
| Range (mg/dL) | 97 – 345 | 63 – 404 | 36 – 312 | 91 – 304 | 36 - 404 |
| Mean Bias(mg/dL) | -3.09 | -4.22 | 4.27 | 2.89 | -0.20 |
| Slope (95% CI) | 0.94 (0.87-1.01) | 0.97 (0.89-1.05) | 0.98 (0.93-1.04) | 0.96 (0.89-1.04) | 0.96 (0.92-0.99) |
| Intercept (95% CI) | 9.2 (-6.9-25.2) | 0.83 (-13-14.8) | 6.5 (-1.6-14.6) | 8.6 (-4.23-21) | 7.1 (1.00-13.2) |
| R | 0.97 | 0.97 | 0.99 | 0.97 | 0.97 |
| $R^2$ | 0.93 | 0.93 | 0.97 | 0.93 | 0.94 |
| RMSE | 17.8 | 19.6 | 10.7 | 15.1 | 16.4 |

*b. Matrix comparison:*

No change in matrix (whole blood).

3. Clinical studies:

*a. Clinical sensitivity:*

Method comparisons were performed at 4 clinical sites to compare performance of the TrueTrack Glucose system with a gold standard method. Self measurements of blood glucose from the forearm were done by patients in duplicate to determine the patient's ability to perform alternate site testing. Four forearm samples were then taken by the healthcare professional from the same patients within 10 minutes. The samples were used to test the comparative devices in duplicate by the healthcare professional. Additional capillary samples were taken from each patient for determination of the patient's hematocrit. In these studies, no effort was made to assure that patients had steady state levels of blood glucose. Results are summarized below by site and combined data. (RMSE = Root Mean Square Error)

**Device vs. Gold Standard (performed by Healthcare Professional)**

| Site | 30 | 31 | 32 | 33 | ALL |
|---|---|---|---|---|---|
| N | 51 | 51 | 47 | 49 | 198 |
| Range (mg/dL) | 102 - 363 | 47 - 346 | 38 – 320 | 83 - 347 | 38 - 363 |
| Mean Bias(mg/dL) | -1.96 | 3.97 | 4.97 | 6.46 | 3.29 |
| Slope (95% CI) | 0.88 (0.79-0.98) | 0.84 (0.77-0.90) | 0.94 (0.87-1.01) | 0.92 (0.84-1.00) | 0.89 (0.85-0.93) |
| Intercept (95% CI) | 22.4 (0.74-44.0) | 28.4 (18.0-38.8) | 14.3 (3.3-25.2) | 19.3 (6.0-32.5) | 21.6 (15.0-28.1) |
| R | 0.93 | 0.97 | 0.97 | 0.96 | 0.96 |
| $R^2$ | 0.87 | 0.93 | 0.94 | 0.92 | 0.92 |
| RMSE | 24.9 | 15.2 | 15.1 | 16.6 | 18.4 |

**Device vs. Gold Standard (performed by Patient)**

| Site | 30 | 31 | 32 | 33 | ALL |
|---|---|---|---|---|---|
| N | 52 | 50 | 48 | 49 | 199 |
| Range (mg/dL) | 102 – 363 | 47 – 346 | 38 – 320 | 83 – 347 | 38 - 363 |
| Mean Bias(mg/dL) | 3.87 | 6.51 | 3.69 | 5.57 | 4.91 |
| Slope (95% CI) | 0.85 (0.76-0.94) | 0.85 (0.77-0.92) | 0.99 (0.90-1.07) | 0.91 (0.80-1.01) | 0.90 (0.86-0.95) |
| Intercept (95% CI) | 35.5 (15.0-56.0) | 29.5 (17.0-42.0) | 5.64 (-8.2-19.5) | 20.4 (1.39-39.5) | 21.0 (13.3-28.7) |
| R | 0.94 | 0.96 | 0.96 | 0.92 | 0.95 |
| $R^2$ | 0.88 | 0.92 | 0.92 | 0.85 | 0.90 |
| RMSE | 23.9 | 18.2 | 19.1 | 24.4 | 21.8 |

**Device performed by Patient vs. Healthcare Professional**

| Site | 30 | 31 | 32 | 33 | ALL |
|---|---|---|---|---|---|
| N | 53 | 51 | 48 | 46 | 198 |
| Range (mg/dL) | 98 – 450 | 53 – 447 | 30 – 316 | 94 – 309 | 30 - 450 |
| Mean Bias(mg/dL) | 7.58 | 1.49 | -0.73 | -0.31 | 2.16 |
| Slope (95% CI) | 0.94 (0.85-1.03) | 0.92 (0.84-1.00) | 1.00 (0.90-1.10) | 0.99 (0.92-1.07) | 0.98 (0.94-1.02) |
| Intercept (95% CI) | 20.7 (0.85-40.6) | 13.5 (-1.28-28) | -0.90 (-17.6-16) | 0.90 (-12.3-14) | 5.8 (-1.9-13.5) |
| R | 0.95 | 0.95 | 0.95 | 0.97 | 0.96 |
| $R^2$ | 0.90 | 0.91 | 0.89 | 0.94 | 0.92 |
| RMSE | 23.7 | 21.4 | 22.7 | 14.9 | 21.3 |

In a subsequent study, the sponsor compared the performance of their device when using samples taken from the fingertip (previously cleared K030703) vs. samples taken from the forearm. Patients were tested only if they had been fasting for at least 3.5 hours prior to testing to make sure their glucose levels were in steady state. The study was performed at one site and included 100 samples. Samples were taken by healthcare professionals. Additional samples were taken to be tested using a gold standard method and to determine the patient's hematocrit. Results are summarized below. (RMSE = Root Mean Square Error)

| | Patient tested | Professional Tested |
|---|---|---|
| N | 100 | 100 |
| Range (mg/dL) | 43 - 280 | 47 - 308 |
| Mean Bias(mg/dL) | 4.08 | 8.11 |
| Slope (95% CI) | 1.01 (0.96-1.06) | 0.98 (0.91-1.04) |
| Intercept (95% CI) | 2.68 (-4.49-9.85) | 11.18 (2.02-20.34) |
| R | 0.97 | 0.95 |
| $R^2$ | 0.94 | 0.90 |
| RMSE | 13.27 | 18.16 |

*b. Clinical specificity:*

Not applicable.

*c. Other clinical supportive data (when a and b are not applicable):*

A SMOG readability test was performed for changes made to the TrueTrack Owner's Booklet, Test Strip insert, and Lancing Device insert. Insert and Lancing Device Insert all include identical text changes. The additional text was assessed according to the NCCLS protocol, and it generated a 7th grade readability assessment. Results of the SMOG test support the readability of product labeling instructions-for-use by the lay user and ease-of-use when using the TrueTrack Smart System for blood glucose testing. In a human factors study questionnaire, 222 patients were routinely asked 13 questions at four different clinical sites. Results are similar to the results found in the original device Clinical Trial Consumer Studies Report (K030703).

4. Clinical cut-off:

Not applicable. See below for recommended reference ranges.

5. Expected values/Reference range:

The sponsor states that test results equal or below 80 mg/dL (4.4 mmol/L) indicate low blood glucose (hypoglycemia), and that test results greater than 250 mg/dL (13.9 mmol/L), indicate high blood glucose **(**hyperglycemia).

**M. Conclusion:**

I recommend that the Home Diagnostics TrueTrack Smart System Blood Glucose Meter, TrueTrack Smart System Blood Glucose Test Strips, and TrueTrack Smart System Glucose Control Solutions (low and high) are substantially equivalent to the legally marketed predicate device.